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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/058,589	04/10/1998	IAN KIMBER	138.41.US01	7637

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FULBRIGHT & JAWORSKI, LLP
1301 MCKINNEY
SUITE 5100
HOUSTON, TX 77010-3095

EXAMINER

WANG, SHENGJUN

ART UNIT PAPER NUMBER

1617

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/058,589

Applicant(s)

KIMBER ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-10, 21, 23, 24 and 26-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-10, 21, 23, 24 and 26-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 11, 2005 has been entered.

Claims Rejection 35 U.S.C. – 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-10, 21, 23, 24 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teng et al. (of record) in view of Britigan (Advances in Experimental Medicine and Biology, Vol. 357, page 143-156, 1994), Morinaga Milk Inc. (JP 07-233086), and De Lacharriere et al. (US Patent 5,658,581).

2. Teng et al teach a method of treating dermal inflammatory disorder of human comprising the step of administering a pharmaceutically effective amount of lactoferrin product. See, particularly, page 4, lines 21-30.

3. Teng et al. does not teach expressly the treatment of the particular dermal disorder herein or the employment of biological analog or fragments of lactoferrin.

However, Britigan teaches generally that lactoferrin are known to be useful as an anti-inflammatory agent. See, particularly, page 151, the summary and conclusion. Morinaga Milk

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Inc. teaches that lactoferrin or its derivatives are known to be useful for treating various skin disorders, including allergic dermatitis. See, the abstract. De Lacharriere et al. teach that lactoferrin is known to be useful for treating or preventing skin inflammation induced by certain cosmetic or pharmaceutical allergen, See, particularly, the abstract, column 3, line 4 bridging column 4, line 39, and the claims.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ lactoferrin for treatment dermal disorder, particularly, skin inflammation, including contact dermatitis or psoriasis.

1. A person of ordinary skill in the art would have been motivated to employ lactoferrin for treatment dermal disorder, particularly, skin inflammation, including contact dermatitis or psoriasis because lactoferrin is well known to be useful for anti-inflammation, and is further known particularly useful for treatment of skin inflammation, particularly, allergic dermatitis. Regarding the functional limitation in claim 5, “reducing Langerhans cell migration or accumulation of dendritic cell in lymph nodes” ; claim 7, i.e., “a local immune response characterized by increased production of TNF- α ” and in claim 21, “a dermal inflammatory response that is characterized by accumulation of dendritic cell in lymph nodes”, note such limitation is not seen to render the claimed invention much patentable weight since the ultimate method, e.g., administering lactoferrin to person with dermal inflammatory disorder such as contact dermatitis, UV-induced inflammation, psoriasis, skin aging or diaper rash, is not further limited by such functional language. The instant claims are directed to affecting a biochemical pathway with an old and well known compounds. The argument that such claims are not directed to the old and well known ultimate utility (inflammation caused by allergen) for the

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compounds, e.g., lactoferrin, are not probative. It is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter.

Applicant's attention is directed to *In re Swinehart*, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103. Further, a method for treatment of a symptom would have been reasonably expected to be effective for the treatment of the symptom despite the underline etiology that causes the symptom. Finally, the optimization of a result effective parameter, e.g., effective amount of therapeutical agent, is considered within the skill of the artisan. See, *In re Boesch and Slaney* (CCPA) 204 USPQ 215. As to the newly added limitation "that is exposed to an allergen," note allergic dermatitis is caused by exposing to allergen.

Regarding the limitation "a composition consisting essentially of lactoferrin and a pharmaceutically acceptable carrier," note, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of" for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). Further, since lactoferrin has been taught

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or suggested to be useful in treating dermal inflammation, it would have been obvious to one of ordinary skill in the art to make a composition, wherein lactoferrin is the active ingredient. In fact, in De Lacharriere et al. (US Patent 5,658,581), lactoferrin is used as the only anti-inflammatory agent.

Response to the Arguments

Applicants' amendments and remarks submitted April 11, 2005 have been fully considered, but found unpersuasive.

As to the limitation "reducing langerhans cell migration or accumulation of dendritic cell in lymph nodes" recited in claims 5 and 21, it is noted that such limitation is a functional limitation. As discussed above, the limitation fails to distinct the claimed invention from the cited prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER
Shengjun Wang
Primary Examiner
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